

likely to yield a number of spurious associations because of the difficulty of multiple comparisons.<sup>4</sup> On the other hand, one could miss an important clue by not splitting.

The problem is well illustrated by studies of the UKAEA workforce. Earlier papers reported an unexpected relation between radiation and prostate cancer,<sup>5,6</sup> which caused concern among scientists and workers. However, Atkinson and colleagues' report<sup>1</sup> now finds, in more recent years, no evidence for such an association and concludes that previous observations can be accounted for by chance or exposure to some non-radiation hazard that has now disappeared from the workplace.

How do we deal with catch-22 and catch-23? There is no ideal answer, but some approaches seem to make sense. Studies of nuclear workers should be continued, but the focus should be on the combination of such studies, such as that of the National Radiation Protection Board Registry<sup>7</sup> or the international combined studies coordinated by the International Agency for Research on Cancer.<sup>8</sup> This approach—ie, combining studies—will increase statistical power and allow direct comparison of results across studies: consistency of findings is a very important criterion of causality.<sup>9</sup> Checking for consistency should help in assessing the reality of associations for a specific cancer observed in a specific study. Both lumping and splitting should be used in epidemiological studies, but the emphasis must be given to a-priori hypotheses when interpreting results. An isolated finding with respect to a specific cancer certainly warrants attention, but does not warrant over-interpretation. Such associations cannot be ignored, but further investigation is required before alarm bells are rung. Literally millions of

people worldwide are occupationally exposed to radiation. If future studies take account of the above principles, studies of the type done by Atkinson and colleagues<sup>1</sup> will play an even more important part in assessing the validity of our current radiation protection standards and avoid unnecessary alarm to workers and the general public.

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I declare that I have no conflict of interest.

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## Implications of the draft European Union services directive for health care

In June, 2004, the UK Department of Trade and Industry completed a public consultation on a draft European Union (EU) directive. If enacted, the directive could have profound implications for health-care provision in all 25 EU member states because, when finalised, it will have to be transposed into national law.<sup>1</sup> The publication of the services directive has attracted an unusual amount of controversy because of its potential to affect member states' control of health and social services, responsibilities that are currently largely outside EU competence. States' supposed autonomy in these areas has always been qualified by the Union's basic task to create a cross-border or European internal market in goods and services. Now Frits Bolkestein, the internal market commissioner, has for the first time set out proposals designed to remove barriers to cross-border trade that arise from the way services are regulated by national governments. This

sector includes everything from estate agencies to amusement parks, and importantly, health-care and social services. The European Commission has argued that "economic growth and job creation afforded by the services sector" has been hampered by overly burdensome regulation, the Commission's only rationale for which can be trade protectionism, it conjectures.<sup>2</sup> It claims that although the service sector accounts for around three-quarters of economic activity in the EU, cross-border trade in services is being unnecessarily hindered by "red tape".<sup>3</sup>

But the distinction between trade-impeding red tape and reasonable regulation is not hard and fast and the fear is that in promoting an internal market that gives commercial providers more transborder opportunities, the Bolkestein directive will dilute governments' powers to regulate businesses operating on their territories,

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European Commissioner Frits Bolkestein

protect the public sector, and guarantee service access and quality. Feelings are running so high that a public demonstration was mounted in Brussels in June this year, perhaps the first time a draft directive has attracted such attention. Fears are bolstered by criticism of similar initiatives pursued by the EU and others within the World Trade Organization.<sup>4</sup> Unsurprisingly, the deregulatory agenda is widely supported by the business lobby, including chief executives of European services corporations who argue that deregulation “brings efficiency and modernization, and is crucial in attracting foreign direct investment”.<sup>5</sup>

At the heart of the draft directive is a set of prohibitions or limitations on governmental rules and regulations that the Commission contends member states frequently use to impede the right of private firms to establish where they choose (one of the fundamental economic freedoms on which the Union is based). The prohibitions apply to all services that are deemed to be economic activities rather than purely public services. The inclusion of health and social care in the economic activity category is the first explicit statement by the Commission that it views them as commodities, which can and should be traded across the borders of the Union.

The directive employs various techniques to control government policy. For example, certain proposals are designed to simplify administrative rules on licensing. Draft article 14 requires, among other things, the

abolition of regulations that require businesses to register with authorities, and prohibits economic or market tests, such as those governments frequently use to control the supply of services. Draft article 15 requires national governments to show that domestic legislation governing the establishment of service providers is both necessary and proportional. If both cannot be shown, the legislation must be amended. Other rules promote competition among regulatory authorities. For example, chapter 3 of the directive lays down the country-of-origin principle according to which a service provider operating legally in one member state can choose to market its services on a temporary basis in another state without having to comply with different rules in the host country. But “temporary” is not defined. And draft article 27-3 allows providers to rely on professional indemnity guarantees taken out in other states so long as they are “equivalent, or essentially comparable as regards purpose”.

The directive has several direct implications for national health-care systems. For example, article 23 codifies recent European Court judgments on the cross-border movement of patients. This restricts the circumstances in which national governments can refuse authorisation and reimbursement for patients seeking treatment in other EU member states.

The provisions will also affect health and social services in the UK not directly provided by the National Health Service, a growing category given the greater involvement of the private sector. Regulations that govern the territorial distribution of service providers, such as those used to ensure access to community pharmacies for the poorest and least mobile, are threatened.<sup>6</sup> The licensing procedures for NHS foundation trusts and the rules establishing general practitioner services, dental practices, and care homes could all fall within the scope of this legislation. The country-of-origin principle raises the prospect of a race to the bottom in regulation of the employment and care standards of commercial providers. Thus many of the standards that regulate the new NHS market could come under challenge.

The draft directive is a significant attempt to increase the EU’s capacity to regulate health and social care within the framework of free-trade rules, and envisages the creation of a European-wide market in health-care services. It is controversial because it raises, but does not resolve, issues about the guardianship and direction of health policy in Europe. Under the primary legislation of the EU, the EC Treaty—the organisation and delivery of health services and medical care—is a responsibility of member states.<sup>7</sup> The directive undermines this division of power because although the treaty requires that “a high level of human health protection shall be ensured in the definition and implementation of all Community policies and

activities”, there is no constitutional guarantee for the level of protection individual states have elected to pursue.<sup>7</sup> If this vacuum in the EU’s constitution is not filled, the Union will be diminished as a force for progress.

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We declare that we have no conflict of interest.

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## Obesity and culture

If the overweight (47% of men and 33% of women) and obese groups (21% and 23%, respectively) are combined, over two-thirds of men and over half of women in England were either overweight or obese in 2001.<sup>1</sup> The problem in the USA is no less severe: 65% of adults—about 130 million people—are either overweight or obese, and the cost of this health problem to the nation has been estimated at US\$117 billion.<sup>2</sup>

In the USA, the National Institutes of Health obesity research strategy plan<sup>2</sup> has recently been released; in the UK, the National Institute for Clinical Excellence is currently developing guidelines to inform doctors’ choices of treatment for their overweight and obese patients. Although the stakeholders in the consultation do not include any of

the multinational food companies, they do include Atkins Nutritional Inc, Slimming World, and Weight Watchers UK. These highly profitable organisations arguably provide a ready solution to obesity; they also offer a focus for a more disparate malaise, of which overeating and obesity could be symptoms. This malaise, which manifests itself in diverse, but increasingly visible ways, needs to be addressed.

The first question, however, must be how rising levels of obesity were overlooked until they reached epidemic proportions. The trend towards bigger waist-lines and oversized blood pressure cuffs must surely have been noted by many practitioners, from general practitioners to cardiologists to public-health doctors, and yet the problem was not registered at a policy-making level before it became crisis management. Statistical analysis and policy-making clearly did not join up. Where rising levels were noted, there was a palpable unease about boldly stating that we are all getting fatter, which might be perceived as a moral judgment and a condemnation of certain lifestyle choices. But even if we had been prepared to come out and say it, would we have been willing to address the reasons why?

As we go into an all-out attack on our current “greatest killer”, we need to stop and consider the likely consequences of public policy made in the face of crisis. Recently, Grossman and Rashad<sup>3</sup> linked the price of cigarettes with increases in the number of obese people, and suggested that efforts to curb cigarette smoking could have had unintended side-effects, which are now having to be tackled. The UK House of Commons Select Committee’s report on obesity suggests that obesity “will soon surpass smoking as the greatest cause of premature loss of life”.<sup>4</sup> But could obesity be linked to tobacco consumption—with a decrease in one leading to a rise in the other?

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